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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,583	05/23/2006	David Borsook	04843/144002	4263

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
BOR, HELENE CATHERINE	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
10/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,583	BORSOOK ET AL.	
	Examiner	Art Unit	
	HELENE BOR	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *journal article*.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 1-5, 9-11, 14-15 & 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Beccerra et al. (US Patent No. 2002/0042563 A1) and further in view of Lariviere et al. (William R. Lariviere, Elissa J. Chesler, and Jeffrey S. Mogil. "Transgenic Studies of Pain and Analgesia: Mutation or Background Genotype?". J. Pharmacol. Exp. Ther., May 2001; 297: 467 – 473; enclosed herein).

Claim 1-3, 6-7, 14, 16-17, 22-26, 32-33, 36-35, 42-43, 46, 48-49, 50 & 53: Beccerra teaches a method for identifying a target for analgesic therapy (Page 2, Para 0013 & 0016, Page 19, Para 0232 & Page 39, Para 0469). Beccerra teaches providing a first and a second non-human subject (Page 14, Para 0179). Beccerra teaches performing an fMRI on the brain of said first and second subjects during or following administration of a painful stimulus (Page 38, Para 0457-0460). Beccerra teaches comparing the results of said fMRI on the brain of said first subject with the results of said fMRI on the brain of said second subject to identify a brain region that is differentially activated in response to said painful stimulus, said brain region being a target for analgesic therapy (Page 14, Para 0179, Page 39, Para 0462 – 0464). Beccerra teaches a method, wherein said method further comprises the steps of administering an analgesic (Figure 16, Element 1606). Beccerra teaches performing a second fMRI on the brain of said first and second subjects during or following a second administration of said painful

stimulus (Figure 16, Element 1612 & 1616). Berrecca teaches comparing the results of said second fMRIs to identify a brain region that is differentially activated in response to said painful stimulus in the presence of said analgesic, said brain region being a target for analgesic therapy (Page 14, Para 0178, Page 38, Para 0459 & Page 39, Para 0462 – 0464 & 0469). Beccerra teaches the use of human and animal test subjects (Page 14, Para 0179) but fails to teach the subjects require a having a genetic-based difference in nociception. However, Lariviere explains that examining transgenic (Page 467-468, *Construction of Knockout Mice*) non-human subjects against pure background non-human subject, one could understand the complex relationship between the "normal" strain and the susceptible strain (Page 472, Right Column). It would have been obvious to one of ordinary skill in the art to modify the method of Beccerra to include the test subject as taught by Lariviere in order to avoid the problems of hitchhiking donor gene and epistasis that can negatively affect the accuracy of the result (Page 468).

Claim 3, 24 & 34: Beccerra teaches a method, wherein, prior to, simultaneous with, or following administration of said painful stimulus, an analgesic is administered to said first subject and said second subject and, in comparing the results, said brain region is differentially activated in response to said painful stimulus, said analgesic, or both (Page 25, Para 0298 & Page 38, Para 0458).

Claim 4-5 & 15: Beccerra teaches a method, wherein said method further comprises the step of assessing gene expression in said target brain region identified in step of comparing results to further identify a gene or gene product that is differentially

expressed, wherein said differentially expressed gene or gene product is a target for analgesic therapy (Page 38, Para 0458 & Page 39, Para 0465 & 0469).

Claim 8 & 18: Beccerra teaches using animals as subjects (Page 14, Para 0179) and teaches the experiment being adapted for testing gene products or therapies (Page 1, Para 0004, Page 19, Para 0232, Page 25, Para 0295 & Claim 23). Beccerra does not specifically mention wherein said first subject and said second subject are rodents with of different strains such as 129P3, A, AKR, BALB/c, C3H/He, C57BL/6, C57BL/10, C58, CBA, DBA/2, RIIIS, SM, LP, SJL, and SWR. However, Lariviere teaches using DBA/2 strain for studies of nociception since its phenotype is consitently moderate (Page 471, Last Right Paragraph – Page 472, Left Paragraph).

Claim 9-11, 27-29 & 37-39: Beccerra teaches a method, wherein said painful stimulus is an acute pain stimulus. Beccerra teaches a method, wherein said painful stimulus is a chronic pain stimulus. Beccerra teaches a method, wherein said chronic pain stimulus is neuropathic pain, arthritic pain, or cancer pain (Page 25, Para 0296).

Claim 12, 19, 30-32, 40-41, 47 & 54: Beccerra teaches, wherein said painful stimulus is a stimulus that induces a hypersensitive response (Page 39, Para 0465). Beccerra teaches testing drugs, which has desirable effects. It would have been obvious to one of ordinary skill in the art that a desirable effects for testing would be a hypersensitive response especially when evaluating drugs (Page 39, Para 0465).

Claim 13: Beccerra teaches, wherein said first subject and said second subject are conscious (Page 37, Para 0438). Beccera'563 doesn't specifically teach the subjects

being conscious. However, it is obvious to one of ordinary skill in the art that the subject were conscious to provide feedback to the VAs scale.

Claim 20, 44 & 51: Beccerra teaches, wherein said analgesic is a channel blocker, antidepressant, μ-opioid receptor agonist, κ-opioid receptor agonist, cannabinoid receptor agonist, nicotinic receptor agonist, or adrenergic receptor agonist (Page 8, Para 0129).

Claim 21, 45 & 52: Beccerra teaches a method, wherein said analgesic is morphine (Page 15, Para 0192).

Response to Arguments

3. Applicant's arguments with respect to claim 1-54 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768